



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

September 24, 2014

IN THE MATTER OF:

An Application for a Certificate of Need filed
Pursuant to Section 19a-638, C.G.S. by:

Notice of Agreed Settlement
Office of Health Care Access
Docket Number: 14-31901-CON

Hartford Hospital


**Acquisition of a 3T Magnetic
Resonance Imaging Scanner**

To:

Barbara A. Durdy
Director, Strategic Planning
Hartford Healthcare
181 Patricia Genova Drive
Newington, CT 06111

Dear Ms. Durdy:

This letter will serve as notice of the approved Certificate of Need Application in the above-referenced matter. On September 24, 2014, the Agreed Settlement, attached hereto, was adopted and issued as an Order by the Department of Public Health, Office of Health Care Access.



Kimberly R. Martone
Director of Operations

Enclosure
KRM:lkg, amv



**Department of Public Health
Office of Health Care Access
Certificate of Need Application**

Agreed Settlement

Applicant: Hartford Hospital

Docket Number: 14-31901-CON

Project Title: Acquisition of a 3.0 Tesla MRI Scanner to Conduct Research Studies

Project Description: Hartford Hospital, Olin Center for Neuropsychiatry (“Hospital” or “Applicant”) seeks authorization to acquire a new 3.0 Tesla (“3T”) Magnetic Resonance Imaging (“MRI”) scanner to use for functional research. The total capital expenditure associated with this proposal is \$3,342,905.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need (“CON”) application in the *Hartford Courant* on November 19, 20 and 21, 2013. On February 14, 2014, the Office of Health Care Access (“OHCA”) received the CON application from the Applicant for the above-referenced project and deemed the application complete on June 27, 2014. OHCA received no responses from the public concerning the Applicant’s proposal and no hearing requests were received from the public pursuant to Connecticut General Statutes (“Conn. Gen. Stat.”) § 19a-639a. Deputy Commissioner Davis considered the entire record in this matter.

Findings of Fact and Conclusions of Law

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

1. The Applicant is an 867-bed¹ non-profit acute care hospital located at 80 Seymour Street and 200 Retreat Avenue in Hartford, Connecticut. Ex. A, p. 133.
2. The Institute of Living (“IOL”) is a division of the Hospital. IOL is a not-for-profit center for comprehensive patient care, research and education in the fields of behavioral, psychiatric and addiction disorders. Ex. A, p.8.
3. The Olin Center for Neuropsychiatry Research (“Olin Center”) is an integral component of the IOL. It is located at 400 Washington Street in Hartford, Connecticut. The Olin Center conducts continuing research studies in the areas of cognitive function including normal aging, working and long term memory, error monitoring, language and attention. The Olin Center is also involved in research on multiple neuropsychiatric diseases including depression, schizophrenia, Alzheimer's disease, manic-depressive illness and alcohol/drug abuse. Ex. A, p. 8.
4. The Olin Center is the only neuropsychiatry research facility within the Hospital’s service area. Ex. A, p. 13.
5. On June 3, 2002, OHCA granted the Olin Center approval (DN 02-502-CON) to operate an Allegra 3T MRI (“Allegra MRI”) scanner to conduct research studies on humans. OHCA CON Determination, Report Number 13-31871-DTR.
6. On November 27, 2012, the Applicant purchased a Siemens Skyra 3T MRI (“Skyra MRI”) scanner to replace the existing Allegra MRI. Ex. A, pp. 9-10, 28.
7. The Skyra MRI was placed in service in January 2013. Ex. C, p. 146.
8. The Applicant initially intended to use the Allegra MRI until May 2016 due to the requirement that the same scanner be used throughout each research study to ensure a consistent and accurate study comparison. Ex. A, pp. 9-10, OHCA CON Determination, Report Number 13-31871-DTR.
9. Under Report Number 13-31871-DTR, issued on October 28, 2013, OHCA determined that the Hospital was required to file a CON application for the acquisition of the above-mentioned MRI scanner. OHCA CON Determination, Report Number 13-31871 -DTR.

¹ Includes 48 bassinets

10. After Report Number 13-31871-DTR was issued by OHCA, the number of funded research applications requiring the use of MRI scanning, as well as anticipated applications, has increased by over 60%. Ex. A, pp. 10-11.
11. The Applicant intends to retain the Allegra MRI rather than take it off-line, as originally planned. Ex. A, pp. 10-11.
12. While conventional MRI results in snapshots of what is inside the body, functional² MRI (“fMRI”) technology “produces movies starring the brain.” It shows researchers where the blood is rich in oxygen and where it is not, resulting in images that help to diagnose disorders related to speech, hearing, vision and motor skills. Ex. A, p. 9; www.apa.org/research/tools/fmri-adult.pdf
13. An article submitted by the Applicant, “Toward Discovery Science of Human Brain Function” published in the Proceedings of the National Academy of Sciences, March 9, 2010, supports the use of the Skyra 3T platform required for running Connectome³ research sequences for neurosciences in need of fMRI scanning. Connectome is the flagship MRI brain anatomy project being performed at the Olin Center. Ex. A, p. 17 at Exhibit 3, pp. 30-36.
14. The need for a second MRI at the Olin Center is based on the following factors:
 - a. Increase in the number of funded research studies;
 - b. Inability to accommodate all ongoing studies with a single MRI scanner; and
 - c. Obsolescence of the Allegra MRI.Ex. A, p. 11.
15. In the last several years, the number of scientific research projects at the Olin Center has grown substantially. The Olin Center currently supports multiple National Institutes of Health (“NIH”) funded research projects and funded research sponsored by the Brain and Behavior Research Foundation, the Donoghue Foundation, Autism Speaks and local funders. There are several proposals currently submitted to NIH from Olin Center investigators awaiting funding decisions. Ex. A, p.12.
16. Current research studies include a 2,000-person study of alcoholism in college students, a 700-person study of psychosis endophenotypes and a 325-person study of imaging endophenotypes of bipolar disorder. Ex. A, p. 14.
17. Current funding from primary projects and from collaborator subcontracts represent a broad array of research ranging from schizophrenia, bipolar disorder, alcohol, cannabis and cocaine

² Functional magnetic resonance imaging or functional MRI (fMRI) is a functional neuroimaging procedure using MRI technology that measures brain activity by detecting associated changes in blood flow.
<http://fmri.ucsd.edu/Research/whatisfmri.html>

³ A Connectome is a comprehensive map of neural connections in the brain. The Human Connectome Project aims to provide an unparalleled compilation of neural data, an interface to graphically navigate this data and the opportunity to achieve never before realized conclusions about the living human brain.
www.humanconnectomeproject.org/

abuse, autism spectrum disorders, Alzheimer's disease, multiple disease endophenotypes, normal adolescent brain development, ADHD, pathological hoarding, OCD, conduct disorder, exercise? and other topics. Ex. A, p.12.

18. The maximum number of MRI research subject slots available per week on one scanner is twenty-five (25), based on one scanner running five days a week and up to ten hours per day. Typical slots are from 1.5 to 3 hours.⁴ Ex. A, p.11.
19. Currently, there are seventeen research studies utilizing 30 slots per week; 15 slots on each of the two MRIs. The Olin Center also has pending grants for eleven NIH research studies. These studies will require utilizing an additional 5.5 slots on the Allegra MRI and 13.5 slots on the Skyra MRI for a total of 28.5 slots. Combining the current and pending studies will require a total of 49 slots. Ex. A, p. 11.
20. With the introduction of the Skyra MRI, the Olin Center will be able to conduct additional large-scale projects or support other planned research studies. Ex. A, pp. 13, 17.
21. Over the past several years, the scale and type of research conducted by the Olin Center has grown substantially, creating a need for enhanced technological capacity and cutting edge imaging. Current research protocols require a variety of magnetic resonance techniques, including structural MRI, fMRI, proton spectroscopy and angiography. The Skyra MRI will accommodate these various techniques. Ex. A, p. 18.
22. Siemens will only guarantee the maintenance of the Allegra MRI scanner until December 31, 2016. Ex. A, pp. 9, 156.
23. The Allegra MRI is over ten years old and will not undergo any further development or updating by Siemens. Parallel-coil imaging required for high quality images in a shortened acquisition time and without compromising the ability to acquire meaningful data will not be made available for this scanner. Without the updated coil, the Allegra MRI will lag technologically and scan times will be prolonged, creating a problem for the majority of the research subject population: restless children/teenagers, claustrophobic patients or patients with ADHD and anxiety disorders, anxious/paranoid patients with major mental illnesses and patients with drug-induced restlessness. Ex. A, p. 9.
24. The Skyra MRI is equipped with parallel-coil imaging. The fMRI technology uses a combination of magnet and radio frequencies to study oxygen flow and metabolism in areas of the brain. The Skyra MRI provides access to additional neuroimaging techniques that facilitate existing studies and enable scanning new types of subjects. Ex. A, p. 9.
25. The Skyra MRI offers software options for online movement visualization or correction, and methods for real-time fMRI modeling to ensure data quality for research participant groups who are hard to recruit, or who refuse to be re-scanned in an additional session should they provide poor data because of movement. Ex. A, p.12 .

⁴ Based on 3 hours per scan time the maximum number of scans than can be performed during 10 hours per day, 5 days per week for a 50-week year is 833 scans and based on 1.5 hours the maximum number is 1,666 scans.

26. Since the Skyra MRI is a wide-bore scanner, and wide-bore scanning capacity is limited on the main campus of the Hospital, on rare occasions, there may be a need for clinical usage. Clinical use will be limited to no more than ten percent (10%) of the total usage and will most likely be less, as it is projected that the research studies will keep the new scanner at or near full capacity. Ex. A, pp. 14; Ex. C, p. 148.
27. The Olin Center's historical and projected MRI utilization is as follows:

TABLE 1
HISTORICAL AND PROJECTED MRI UTILIZATION
BY NUMBER OF SCANS BY FISCAL YEAR

Description	Fiscal Year						
	2011	2012	2013	2014*	2015	2016	2017
Allegra 3T MRI	914	698	583	250	650	300	300
Skyra 3T MRI**	-	-	183	450	1,953	1,884	1,516
Pending research studies	-	-	-	-	425	425	425
Total Scans	914	698	766	700	3,028	2,609	2,241

*Annualized utilization based on actual 7 months utilization from October 2013 to April 2014.

** The Skyra MRI scanner was placed in service in January 2013.

Ex. A, pp. 15-16; Ex. C, pp. 150, 154.

28. The decline in utilization from 2011-2013 is due to the winding down of existing studies at the time and new studies were less available due to the increasing obsolescence of the Allegra MRI scanner. Ex. C, p. 150.

29. The following table reports the projected number of scans for FY 2015, 2016 and 2017 including current research studies, studies awarded but not yet implemented, and pending applications.

**TABLE 2
HISTORICAL AND PROJECTED MRI UTILIZATION**

Research Study Grants	Current			Projected by Fiscal Year		
	Allegra	Skyra	Total Scans per week	2015	2016	2017
Current						
UCONN Steffens	0	2	2	100	100	100
Tolin Hoarding	0	1	1	77	77	77
College Alcohol	2	0	2	100	0	0
Pearlson PARDIP Bipolar Study	2	0	2	100	100	100
HH Obesity	0	3	3	150	150	0
Assaf Autism/Schizophrenia	0	2	2	100	100	100
Yale CTNA	4	0	4	200	200	200
Glahn Bipolar	0	1	1	50	50	50
Pearlson Psychosis NIMH MERIT Award	2	0	2	100	0	0
Pearlson COG Rehab	1	0	1	50	0	0
HH Cardiology/Lipid	1	0	1	50	0	0
UCONN MJ	0	1	1	50	0	0
UCONN HIV Exercise	1	0	1	50	0	0
Karen Blank Alzheimer	0	2	2	100	100	0
O.C. Studies	2	2	4	200	200	200
Additional Studies, combined	0	1	1	50	50	0
Total Current Slots	15	15	30	1,527	1,127	827
Total Current Scans			1,500*			
Pending or Awarded						
Pearlson Alcohol/Driving #2	0	3	3	150	150	150
Stevens Emotion Adolescence	0	2	2	67	64	15
Pearlson BSNIP-2	0	3	3	150	150	150
Oncology/Chemo-Memory	0	2	2	100	100	100
Pearlson/Stevens Driving MJ	0	1.5	1.5	58	57	58
Stevens/Pearlson ADHD	0	1	1	121	121	121
Pearlson/Stevens Affective	0	1	1	50	50	50
Dager K Award (Spectro)	0	1	1	50	50	50
Glahn UO1	0	3	3	200	185	165
K. Carroll	0	2	2	100	100	100
Pearlson PerR01 Impulsivity NIMH	0	1.5	1.5	75	75	75
Pearlson NIDA Obesity NIDA	0	4.5	4.5	70	70	70
Pearlson NIMH Alcohol/Behavioral NIAAA	0	2	2	100	100	100
Diefenbach TMS Research NIMH	0	1	1	50	50	50
Glahn Bipolar	0	1	1	50	50	50
Assaf HHC Functional Neurosurgery	0	1	1	50	50	50
Additional Studies, combined	0	0.5	0.5	60	60	60
Total Pending or Awarded Slots	0	28.5	28.5	1,501	1,482	1,414
Total Pending or Awarded Scans			1,425**			
Grand Total			1,925	3,028	2,609	2,241

*30 scans per week times 50 weeks.

**28.5 scans per week times 50 weeks.

Ex. C, pp. 152, 154.

30. The Applicant anticipates an operational loss associated with the Skyra MRI in FY 2014 through FY 2016 due in part to the annual depreciation⁵ expense of \$545,974 resulting from the acquisition of the scanner.

**TABLE 3
PROJECTED INCREMENTAL REVENUES AND EXPENSES**

Description	FY 2014	FY 2015	FY 2016
Revenue from Operations	\$268,439	\$284,545	\$304,464
Total Operating Expenses	\$991,329	\$996,346	\$1,003,714
Gain/(Loss) from Operations	(\$722,890)	(\$711,801)	(\$699,250)

Ex. A, p.140.

31. The Applicant projects overall operational gains of \$50.6 million in FY 2014, \$17.49 million in FY2015 and \$8.06 million in FY2016.

**TABLE 4
APPLICANT'S PROJECTED REVENUES AND EXPENDITURES WITH THE PROPOSAL**

	FY 2014	FY 2015	FY 2016
Revenue from Operations	\$1,144,265	\$1,179,715	\$1,222,031
Total Operating Expenses	\$1,093,659	\$1,162,224	\$1,213,970
Gain/(Loss) from Operations	\$ 50,606	\$ 17,491*	\$ 8,061**

Note: figures are in thousands.

* Decline in gain from operation is due to projected increases in the following expenses: supplies and drugs, salaries and fringe benefits and depreciation.

**Decline in gain from operation is due to projected increases in the following expenses: supplies and drugs and salaries and fringe benefits.

Ex. A, p.140.

32. The proposed scanner will be used primarily for research purposes and will have no impact on payer mix or access to clinical services at the Olin Center. Ex. C, p.148.
33. There will be no change in access for the patient population served by this proposal, in particular Medicaid patients. Ex. C, p.148.
34. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))
35. This CON application is consistent with the overall goals of the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
36. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
37. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

⁵A method of allocating the cost of a tangible asset over its useful life.

38. The Applicant has satisfactorily demonstrated that its proposal is primarily for research purposes. Therefore, it has no impact on the accessibility and cost effectiveness of health care delivery in the region. The proposal has the potential to improve the quality of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5))
39. The Applicant has shown that there will be no change in access to the provision of health care services to the relevant populations and payer mix since the proposed equipment is mainly for research purposes. (Conn. Gen. Stat. § 19a-639(a)(6))
40. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7))
41. The utilization of existing health care facilities and health care services in the Applicant's service area supports this application. (Conn. Gen. Stat. § 19a-639(a)(8))
42. The Applicant has satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))
43. The Applicant has satisfactorily demonstrated that the proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013).

The Applicant is an 867-bed non-profit acute care hospital located at 80 Seymour Street and 200 Retreat Avenue in Hartford, Connecticut. *FF1* The Olin Center is a component of the Institute of Living, a division of the Hospital. *FF2,3* The Olin Center currently supports multiple NIH-funded research projects and funded research sponsored by the Brain and Behavior Research Foundation, the Donoghue Foundation, Autism Speaks and local funders. Specifically, it is involved in research on multiple neuropsychiatric diseases including schizophrenia, bipolar disorder, alcohol, cannabis and cocaine abuse, autism spectrum disorders, Alzheimer's disease, multiple disease endophenotypes, normal adolescent brain development, ADHD, pathological hoarding, OCD, conduct disorder, exercise and other topics. *FF16,17*

On November 27, 2012, the Applicant purchased a Siemens Skyra 3T MRI ("Skyra MRI") scanner to replace the existing Allegra MRI. *FF6* Originally, the Skyra MRI scanner was meant to replace the existing Allegra MRI scanner for human research purposes. The Applicant initially intended to use the Allegra MRI until May 2016 due to the requirement that the same scanner be used throughout each research study to ensure a consistent and accurate study comparison. *FF7* Under Determination Report Number 13-31871-DTR, OHCA determined that the acquisition of the Skyra MRI required CON approval. *FF6-9* Subsequent to OHCA's determination, the scale and type of research conducted by the Olin Center grew substantially, creating a need for enhanced technological capability and additional capacity. *FF10, 21* As a result, the Applicant proposes retaining the Allegra MRI and receiving authorization for the acquisition of the Skyra MRI. *FF11* Though the Allegra MRI is over ten years old and will not undergo any further development or updating by Siemens, the researchers must use it to complete ongoing studies that are longitudinal in nature and must be conducted over time using the same MRI scanner. *FF10, 23* Due to the technological limitations of the Allegra MRI, the scanner has increasingly become "out-of-step" with techniques used by other neuroimaging researchers. This will decrease the likelihood of Olin Center investigators participating in future multi-site projects, which have become a valuable tool to increase the pace and impact of NIH-sponsored neuropsychiatric research. Ex. A, p. 13

The Skyra MRI is equipped with technological capacity required for advanced research studies such as parallel-coil imaging that produces high quality images in a significantly shortened acquisition time without compromising the ability to acquire meaningful data. In addition, the scanner has software options for online movement visualization or correction, and methods for real-time fMRI modeling to ensure data quality. *FF24,25* Unlike conventional MRI scanners that provide results in snapshots of what is inside the body, fMRI technology produces videos of the brain. It shows researchers where the blood is rich in oxygen and where it is not, resulting in images that will help in the diagnosis of disorders related to speech, hearing, vision and motor skills. *FF12*

Along with the enhanced technology, the Olin Center needs the Skyra MRI due to the increasing number of current, pending and awaiting approval research studies. *FF14,15* The maximum number of MRI research subject slots available per week on one scanner is twenty-five based on one scanner operating five days a week. *FF18* Currently, the Olin Center is running above capacity for one scanner with an average demand of thirty subject slots per week with another 28.5 slots pending approval. *FF19* The number of scans to be performed on the Skyra MRI has been projected to be 3,028, 2,609 and 2,241 scans in Fiscal Years 2015, 2016 and 2017, respectively, tripling the 700 scans expected to be performed in FY 2014. *FF27* The additional MRI scanner capacity will enable the Olin Center to conduct additional large-scale projects, support further planned research studies and attract additional faculty. *FF20* While it is unlikely that many of the pending grant applications will be granted, the Olin Center will continuously apply for research study grants to maximize the usage of the scanners. Ex. A, p. 17 That said, the real need for the Skyra MRI is based upon its advanced technology, not speculative grants. Therefore, OHCA mandates that the Applicant take certain actions as stated in the attached Order.

The proposed Skyra MRI will be used primarily for research to be conducted at The Olin Center, the only neuropsychiatry research facility located within the Hospital's service area. *FF4,32* On occasion there may be a clinical need for the Skyra MRI due to the limited wide-bore scanning capacity on the main campus of Hartford Hospital. *FF26* Overall, this proposal will not have an impact on existing clinical MRI service providers in the area or access to care. Moreover, the proposal will have no impact on the services provided to the Medicaid population since it is being used primarily for research purposes. *FF32,33*

Even though the Applicant has projected an operational loss due to the depreciation expense resulting from the acquisition of the Skyra MRI, this proposal is financially feasible as the acquisition of the Skyra MRI was funded with the Applicant's operating capital and will be supported by the Applicant's overall operational gains of \$50.6 million, \$17.49 million and \$8.06 million for Fiscal Years 2014, 2015 and 2016, respectively. *FF30,31*

This research-oriented MRI will indirectly benefit the strength of the state's health care system by contributing to the quality of health care delivery in the region by facilitating the advancement of neuropsychiatry research. The research conducted will allow the researchers to enhance their knowledge about neuropsychiatric disorders and has the potential to improve future treatment and quality of life outcomes for individuals suffering from these disorders. Therefore, OHCA concludes the Applicant has demonstrated clear public need for the proposal.

Order

NOW, THEREFORE, the Department of Public Health, Office of Health Care Access (“OHCA”) and Hartford Hospital (“Applicant”) hereby stipulate and agree to the terms of settlement with respect to the acquisition of a 3.0 Tesla MRI scanner to conduct research studies within Hartford Hospital’s Olin Center for Neuropsychiatry, as follows:

1. Applicant’s request to acquire a Siemens Skyra 3.0 Tesla MRI scanner to conduct research studies within the Olin Center for Neuropsychiatry is **approved**.
2. Not later than ten (10) business days after the signing of this Agreed Settlement, the Applicant shall provide OHCA with a complete list of research studies currently being performed on the Allegra 3T MRI scanner. The list shall include the name of the study; the name of the Grant approved for the study, the start date of the study; and the anticipated end date for the study.
3. Upon completion of all the research studies currently being conducted on the Allegra 3T MRI scanner, such list being provided to OHCA pursuant to Stipulation #2 herein, the Applicant shall terminate its use of the Allegra 3T MRI scanner and dispose of same.
4. The Applicant shall notify OHCA, in writing, of the disposal of the Allegra 3T MRI scanner not later than ten (10) business days after it has been disposed. Such notification shall provide specifics regarding the date of disposition and how it was disposed.
5. This Agreed Settlement is an order of OHCA with all rights and obligations attendant thereto, and OHCA may enforce this Agreed Settlement under the provisions of Conn. Gen. Stat. §§ 19a-642 and 19a-653 with all fees and costs of such enforcement being the responsibility of the Applicant.
6. OHCA and the Applicant agree that this Agreed Settlement represents a final agreement between OHCA and all parties with respect to this Application. The signing of this Agreed Settlement resolves all objections, claims and disputes that may have been raised by the Applicant with regard to Docket Number: 14-31901-CON.
7. This Agreed Settlement shall be binding upon the Applicant and its successors and assigns.


Signed by STUART K. MARKOWITZ, MD, PRESIDENT
(Print name) (Title)

9-24-14
Date


Duly Authorized Agent for
Hartford Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Department of Public Health Office of Health Care Access on September 24, 2014.

9/24/14
Date:


Lisa A. Davis, MBA, BS, RN
Deputy Commissioner